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LACKENBACH SIEGEL, LLP				
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SCARSDALE, NY 10583				
EXAMINER				
CLARK, AMY LYNN				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/549,740

**Applicant(s)**

LAGUNA GRANJA ET AL.

**Examiner**

AMY L. CLARK

**Art Unit**

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/ISD)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 06/05/2008

### **DETAILED ACTION**

Acknowledgment is made of the receipt and entry of the amendment filed on 04/15/2009 with the cancellation of claims 16-25. Please note that when claims are cancelled, the text should be deleted from the claim so that the claim simply reads, for example: Claim 16: (cancelled).

### ***Election/Restrictions***

Applicant's election of Group I, claims 14 and 15 based upon the cancellation of claims 16-25 in the reply filed on 04/15/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

**Claims 14 and 15 are under examination.**

### ***Specification***

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The

disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because the abstract recites the term "novel" in line 1. It is suggested that the term "novel" be deleted from the language of the abstract. Once the determination of the novelty of a claimed invention has been established and the disclosure of the invention made public and/or patented, the claimed invention is no longer novel or new, since the scope of the invention no longer embraces what is considered "novel". Correction is required. See MPEP § 608.01(b).

### ***Claim Objections***

Claim 14 is objected to because of the following informalities: the term "hydrolisis", found in the last line of the claim, is misspelled. The correct spelling is hydrolysis. Further, "esters" in the last line of the claim is grammatically incorrect. "Esters" should be written ester. Appropriate correction is required.

Claims 14 and 15 are objected to because of the following informalities: the term "esteric" found in line 6 of claim 14 and in line 9 of claim 15 is misspelled. The correct spelling is stearic. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "free fatty acids" in line 9. There is insufficient antecedent basis for this limitation in the claim because Applicants had only defined "primary fatty acids" (in line 4) and "a mixture of ester of the fatty acids" (in line 8). It is unclear if "free fatty acids" are the "primary fatty acids" or esters of the fatty acids or if the "free fatty acids" are other fatty acids present in the composition.

The metes and bounds of Claim 15 are rendered uncertain by the lack of inclusion of "by weight" or "by volume" after the percentage amounts of each of the fatty acids. Are Applicants claiming that the composition comprises these fatty acids in relation to each other or in relation to the total composition? The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14 and 15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over El-Khalaty et al. (Applicants' IDS NPL Reference 4).

El-Khalaty teaches an oil fraction obtained from *Oreodoxa regia* (royal palm) (which is synonymous with *Roystonea regia*) seeds (which reads on fruit, since the royal palm seed contains the fruit) comprising caprylic acid in an amount of 0.4%, capric acid in an amount of 0.4%, lauric acid in an amount of 11.1%, myristic acid in an amount of 5.5%, palmitic acid in an amount of 22.2%, palmitoleic acid in an amount of 9.8%, stearic acid in an amount of 3.0%, oleic acid in amount of 35.3%, linoleic acid in an amount of 17.3% and linolenic acid in amount of 3.5% (See table IV, page 273), which

read on the ranges of each fatty acid component of Applicants' pharmaceutical composition in claim 15. El-Khalaty further teaches that the oil is obtained through a process of first crushing the seed, then defatting the seed followed by subjecting the resulting seed meal to acidic and alkaline hydrolysis (See page 270).

Although El-Khalary does not expressly teach that the oil fraction is a pharmaceutical nor does El-Khalary teach that the composition comprises a mixture of esters of the fatty acids nor does El-Khalary teach that free fatty acids are enriched from ester hydrolysis, the claimed functional properties are inherent to the preparation taught by El-Khalary. The functional properties are inherent to the preparation taught by El-Khalary because the El-Khalary expressly teaches the same composition taught by Applicants based upon the fatty acid profile provided by El-Khalary and the method taught by El-Khalary of obtaining the fatty acid profile from the seeds of royal palm are one and the same as disclosed in the instantly claimed invention of Applicants. Thus, the oil fraction obtained from seeds of royal palm as taught by El-Khalary, a mixture of esters of the fatty acids, and free fatty acids enriched from ester hydrolysis are inherent to the oil fraction composition taught by El-Khalary. Therefore, the reference anticipates the claimed subject matter.

In the alternative, even if the oil fraction composition obtained from *Oreodoxa regia* (royal palm) (which is synonymous with *Roystonea regia*) seeds comprising caprylic acid in an amount of 0.4%, capric acid in an amount of 0.4%, lauric acid in an amount of 11.1%, myristic acid in an amount of 5.5%, palmitic acid in an amount of 22.2%, palmitoleic acid in an amount of 9.8%, stearic acid in an amount of 3.0%, oleic

acid in amount of 35.3%, linoleic acid in an amount of 17.3% and linolenic acid in amount of 3.5% taught by El-Khalary is not identical to the pharmaceutical composition claimed by Applicants with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the oil fraction composition taught by El-Khalary is likely to intrinsically possess the same characteristics (including with respect to the instantly claimed functional effects) of the pharmaceutical composition claimed particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed pharmaceutical composition obtained from the fruit of *Roystonea regia* would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Accordingly, the claimed invention as a whole was at *least prima facie* obvious, if not anticipated by El-Khalary, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the USC 102/103 rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's claimed pharmaceutical composition is different from the oil fraction composition taught by El-Khalary and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

### ***Conclusion***

**No claims are allowed.**



Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY L. CLARK whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy L Clark/  
Examiner, Art Unit 1655